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10/616,125	07/08/2003	Axel Grandt	JM-040	2218

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/616,125

Applicant(s)

GRANDT, AXEL

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,9,10,13,14,17,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,11,12,15,16,18,21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

#### Stent design

Species I: Figs. 1A-1D.

Species II: Figs. 4,5A,5B.

Species III: Figs. 6A-6D,7A,7B.

Species IV: Figs. 8A,8B.

Species V: Fig. 9.

#### Types of tube

Subspecies A: Fig. 1A (hollow).

Subspecies B: Fig. 3 (solid with hollow sections).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Nick Pisano on 2/23/05 a provisional election was made without traverse to prosecute the invention of Species III and Subspecies A, claims 1,2,5-8,11,12,15,16,18,21-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3,4,9,10,13,14,17,19,20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15,16,18,21,22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the wire" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim. The dependent claims are indefinite for depending from claim 15.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,6,15,16,21,23 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone et al. (5882335). Fig. 1 shows a stent **12** formed of a tubular member **28** with a lumen therein and a multiplicity of pores **29** in fluid communication with the lumen. Leone also discloses a therapeutic agent is delivered into the lumen via the proximal end (col. 3, lines 47-49) and is eluted from the stent into the vessel it is implanted in, col. 3, lines 61-65. Fig. 5 shows a coil shape with the pores disposed circumferentially about the exterior surface of the tubular member. Leone also discloses the stent tubular member can be made of shape memory material, col. 5, lines 21-26.

Claims 1,2,6,15,16,21,23 are rejected under 35 U.S.C. 102(b) as being anticipated by Globerman et al. (WO 96/26682). Fig. 5 shows a coiled stent **12** formed

of a tubular member **14** with a lumen **16** therein. Globerman discloses the stent can have a multiplicity of pores in fluid communication with the lumen (page 7, lines 11-15) for a therapeutic agent disposed within the lumen to be eluted from the stent. Globerman also discloses the stent tubular member can be made of shape memory material, page 7, lines 9-10.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al. '335. Leone is explained supra. However, Leone fails to disclose the pores spaced at variable distances with respect to one another. It would have been an obvious matter of design choice to modify the location of the pores, since applicant has not disclosed that using variable distance locations between the pores provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pore locations taught by Leone or the claimed variable distance located pores in claim(s) 5,22 because both stents perform the same function of releasing therapeutic material through pores.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al. '335 in view of Harry (2002/0038146). Leone is explained supra. However,

Leone fails to disclose the pores vary in size or shape with respect to one another.

Harry teaches (Figs. 2,3) pores varying in size on the stent. Harry also teaches (Fig. 8) pores that vary in shape on the stent. It would have been obvious to one of ordinary skill in the art to vary the size or shape of the pores as taught by Harry with the stent of Leone to provide different amounts of therapeutic material released from the stent.

Claims 1,11,12,15,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tower et al. (EP 1057460) in view of Globerman et al. (WO 96/26682). Tower discloses (Fig. 2) a plurality of rings affixed together to form the stent. Tower also discloses that the rings are formed from wire shaped into sinusoidal bends, col. 4, lines 55-58 and col. 5, lines 33-39. However, Tower fails to disclose the tubular members having pores and a lumen with therapeutic material therein. Drug eluting stents are well known in the art. Globerman is explained supra. It would have been obvious to one of ordinary skill in the art to form the stent rings with a lumen to hold pharmaceutical material as taught by Globerman in the stent of Tower et al. to provide a therapeutic stent.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman et al. (WO 96/26682) in view of Slepian et al. (WO 90/01969). Globerman is explained supra. However, Globerman fails to disclose the use of a bioabsorbable polymer to elute the therapeutic agent. Slepian teaches that bioabsorbable polymers (page 11, lines 14-17,24,25) are used as coatings and the material can contain a therapeutic agent for release into the lumen of the patient, page 13, lines 21-38. Slepian teaches (page 15, lines 33-35) the bioabsorbable polymer can be delivered via a tubular

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device, i.e. stent and can be located in the interior of delivery device, page 19, lines 9-11,16-18,25,26. It would have been obvious to one of ordinary skill in the art to use a bioabsorbable polymer with a therapeutic agent in the polymer as taught by Slepian and incorporate the polymer in the stent of Globerman in order to provide a sealing material against the wall and a smoother surface, see Slepian, page 12, lines 6-9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4756. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

